

Notice of Allowability

Application No.

09/905,666

Examiner

Nashaat T. Nashed, Ph. D.

Applicant(s)

GIVER ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed April 6, 2004.
2. ☒ The allowed claim(s) is/are 18,20,49,52,53,56,58,72,74-79,81,83,131,134,181,189 and 211-220.
3. ☒ The drawings filed on 06 April 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

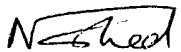
- ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

- ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit: 1652

Art Unit: 1652

The specification has been amended as requested in the communication filed April 6, 2004 and May 14, 2004. Accordingly, claims 18, 49, 51-53, 55, 56, 58, 77, 78, 81, and 189 have been amended, claims 50, 54, 57, 59, 73, and 190-210 have been canceled, and new claims 211-220.

Claims 18, 20, 49, 51-53, 55, 56, 58, 72, 74-81, 83, 131, 134, 181-189, and 211-220 are pending and under consideration.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sharon M. Fujita on May 14, 2004.

The application has been amended as follows:

Delete claims 51, 80, and 182-188.

- Claim 18 An isolated or recombinant polypeptide having lipase activity and comprising a sequence having at least 98% [94%] amino acid sequence identity to the mature region of SEQ ID NO: 55.
- Claim 49 The isolated or recombinant polypeptide of claim 20, wherein the polypeptide comprises the [an] amino acid sequence of [corresponding to] SEQ ID NO: 55.
- Claim 52 The isolated or recombinant polypeptide of claim 18, wherein the [encoded] polypeptide exhibits lipase activity with respect to tributyrin.
- Claim 53 The isolated or recombinant polypeptide of claim 18, wherein the [encoded] polypeptide exhibits lipase activity with respect to tributyrin in N,N-dimethylformamide (DMF).
- Claim 55 The isolated or recombinant polypeptide of claim 18, wherein the [encoded] polypeptide exhibits [enantioselective] lipase activity with respect to neryl-butyrate.
- Claim 56 The isolated or recombinant polypeptide of claim 18, wherein the [encoded] polypeptide exhibits [enantioselective] lipase activity with respect to geranyl-butyrate.

Art Unit: 1652

- Claim 58 The isolated or recombinant polypeptide of claim 18, wherein the [encoded] polypeptide exhibits lipase activity with respect to pentadecanolide.
- Claim 72 The isolated or recombinant polypeptide of claim 18, further comprising a leader sequence.
- Claim 74 The isolated or recombinant polypeptide of claim 18, wherein the polypeptide comprises a secretion signal or a localization signal.
- Claim 75 The isolated or recombinant polypeptide of claim 18, wherein the polypeptide comprises an epitope tag.
- Claim 76 The isolated or recombinant polypeptide of claim 18, wherein the polypeptide comprises a fusion protein comprising one or more additional amino acid sequences.
- Claim 77 The isolated or recombinant polypeptide of claim 18, further comprising a polypeptide purification domain.
- Claim 78 The isolated or recombinant polypeptide of claim 77, wherein the polypeptide purification domain is selected from the group consisting of: an epitope tag, a polyhistidine sequence, and a glutathione S-transferase (GST).
- Claim 79 The isolated or recombinant polypeptide of claim 18, further comprising a methionine residue at the N-terminus.
- Claim 81 The isolated or recombinant polypeptide of claim 18 [80], wherein the polypeptide further comprises a modified amino acid [is] selected from the group consisting of: a glycosylated amino acid, a PEGylated amino acid, a farnesylated amino acid, an acetylated amino acid, a biotinylated amino acid, and an amino acid conjugated to a lipid moiety.
- Claim 83 A composition comprising [one or more] the isolated or recombinant polypeptide of claim 18 and a pharmaceutically acceptable excipient.
- Claim 131 A composition comprising the isolated or recombinant polypeptide of claim 18 and a surfactant.
- Claim 189 An isolated or recombinant polypeptide exhibiting [enantioselective] lipase activity, wherein the polypeptide is encoded by a

Art Unit: 1652

polynucleotide that hybridizes under stringent conditions over substantially the entire length of the mature coding region of [a polynucleotide having a sequence corresponding to] SEQ ID NO: 1, or complement thereof, wherein stringent hybridization conditions are 42 °C overnight in 50% formamide with 1 mg heparin and a 0.2 x SSC wash at 65 °C for 15 minutes, and wherein the polypeptide comprises one or more amino acid residues selected from the group consisting of Lys at position 1, Thr at position 14, Ser at position 17, Arg at position 22, Glu at position 26, Pro at position 31, Gly at position 33, Glu at position 34, Pro at position 35, Pro or Thr at position 37, Ser or Lys at position 41, Gly at position 42, Arg or Glu at position 43, Ala at position 61, Tyr at position 75, Gly at position 96, Ser at position 97, Thr at position 104, Ser at position 107, Ala at position 125, Gly at position 129, Val at position 134, Cys at position 138, Lys at position 141, Lys at position 146, Thr at position 156, Met at position 160, Arg at position 166, and His at position 177, wherein the positions are equivalent amino acid positions with respect to SEQ ID NO: 75.

Claim 219 A composition comprising the isolated or recombinant polypeptide of claim 189 and a surfactant.

Claims 18, 20, 49, 52, 53, 55, 56, 58, 72, 74-79, 81, 83, 131, 134, 181, 189, and 211-220 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1652